

National Institutes of Health National Cancer Institute Bethesda, Maryland 20892

March 8, 2000

Barrett N. Fountos U.S. Department of Energy Office of International Health Programs, EH-63/270CC 19901 Germantown Road Germantown, MD 20874-1290

Dear Mr. Fountos:

Enclosed please find the Scientific and Management Progress Report for the time period 1 November 1999 to 31 January 2000 for the Chornobyl Research Program. I apologize for the delay; however, I have spent a considerable amount of time traveling in the recent past. I believe that you will be pleased with the remarkable progress we have made. I am also enclosing the most recent quarterly reports from the project Directors in Ukraine and Belarus, as well as the most recent quarterly report from Columbia University. Please feel free to contact me if you have any questions regarding this report.

Sincerely,

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National Institutes of Health National Cancer Institute Bethesda, Maryland 20892

Chornobyl Research Program SCIENTIFIC AND MANAGEMENT PROGRESS REPORT 1 November 1999 to 31 January 2000

Submitted by:

Terry L. Thomas, Ph.D.

Date:

1 March 2000

I. Progress on "Epidemiologic Studies of Radiation Induced Thyroid Disease in Belarus (BelAm Thyroid Project) and Ukraine (UkrAm Thyroid Project)

A. BelAm Thyroid Project

The study began in 1997 with the selection of individuals to be included in the study cohort from the file of thyroid dose measurements at the Institute of Biophysics in Moscow (Selection 1). Numerous sources were used to trace subjects, and current addresses were located for 14,033 of these subjects as of December 31, 1999. Invitations to participate in the study are still being sent to subjects from the first selection who did not respond or refused the first invitation. Additional tracing of 1,805 subjects who had previously not responded to screening invitations resulted in the confirmation of 1,355 of their addresses. As of 31 December 1999 these contacts resulted in 7,730 responses, 5,889 of whom were screened, approximately 700 since September. Laboratory testing is complete for 5,800 of these subjects. Exit interviews of 76 subjects indicated that more than 33 percent had to travel from 3 to 12 hours to reach the place of examination. The duration of the examination was reasonable on average; however, a large percentage of subjects expressed interest in receiving more information about the study and in being reimbursed for their travel expenses. The Project Director has been encouraged to develop a brochure describing the project and to add incentives, such as reimbursement for travel. As of 31 December 1999, newly diagnosed thyroid cancer was found in 21 subjects. Selection 1 has not resulted in a sufficient number of responses to achieve the target cohort size of 12,000 subjects. Thus, in December 1999, the remainder of individuals in the dose file were selected and were traced for current address (Selection 2). Initial invitations have been sent to approximately 1,730 of these subjects to be screened in Minsk and 1,016 to be screened by mobile teams during the months of March and April. The data coordinating center prepared a draft of the documentation for the data base, and has developed software for conducting routine edits of the data base.

B. UkrAm Thyroid Project

The study in Ukraine began also in 1997 with the selection of 20,071 subjects to be included in the study cohort selected from the list of people with thyroid dosimetry (Selection

1). Tracing efforts resulted in the location of 13,493 subjects. Of these, 7,387 were invited for screening, beginning in April 1998. As of 31 December 1999, a total of 4,903 subjects had been examined, approximately 900 of them since the end of September. Nine newly diagnosed cases of thyroid cancer have been detected, one within the last quarter. Two additional subjects are suspected to have thyroid carcinoma, but the final pathology was not available at the time of the report. A brochure with a logo for the study has been developed, and is now being sent with new invitation letters which offer reimbursement for travel expenses (equivalent to US \$5). This letter has been sent to subjects not yet invited for examination as well as those who previously refused or didn't respond. These efforts have resulted in a tremendous increase in response, which should be reflected in the next quarterly report. Because Selection 1 has not yet generated sufficient response to achieve the target study population size, a second selection of 20,000 subjects was taken in January. These subjects will be traced for current address during the next quarter.

C. Other Progress

Bi-national Advisory Groups, established to provide scientific advice to project directors, transmitted draft reports of their October meetings to the Project Directors. At the end of the reporting period, the final reports were not available.

A joint meeting of Belarussian, Ukrainian, and American investigators was held 8-10 November 1999 to review the progress of both studies and to discuss numerous issues including: strategies for improving response rates, strategies for contacting and recruiting subjects, screening procedures, frequency of re-screening, standardizing the dosimetry questionnaires, collaboration between Belarussian and Ukrainian investigators, and other issues. Project Directors from both countries have submitted plans for completing the screening of 12,000 subjects by the end of the year 2000.

A draft of a standardized dosimetry questionnaire was prepared at a joint meeting of Belarussian, Ukrainian, and American scientists in January 2000. It is anticipated that the questionnaire will be ready for field testing in late Spring 2000.

The NCI Chornobyl Oversight Panel (COP) had meetings in December 1999 and January 2000 to review status of the studies. A draft list of action items following the discussions of the tri-national meetings in November was reviewed at the December meeting and finalized at the January meeting.

II. Progress on "Study of Leukemia, Lymphoma, and Related Disorders in Ukrainian Clean-up Workers Following the Chornobyl Accident"

The Phase 1 feasibility study which began in November 1997 and was completed in December 1999. The final report dated 17 December 1999 indicated that all tasks were completed successfully, and the study is feasible; however, the question remains as to whether an adequate method can be developed to reconstruct doses.

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A meeting of the joint Ukrainian-American Leukemia Working Group was held for November 15-16, 1999 to review the status of the pilot study and discuss recommendations for future work. The consensus of the Working Group was that a Phase 2 protocol should be developed, and Dr. Geoffrey Howe was asked to chair the protocol-writing effort. NCI approved a continuation of the pilot phase while the Phase 2 proposal is being developed and proceeding through the approval process. During this interim phase, the following activities will be conducted: Test improvements in the proposed dosimetric procedures in the expectation of creating a sufficiently accurate dosimetry model; ensure that authorities in the five new oblasts will cooperate fully, as was the case in the test oblast Dniepropetrovsk; determine that locating and interviewing representative cleanup workers can be done satisfactorily in the five additional oblasts where Phase 2 would be performed.

A working draft of the proposal was circulated to Ukrainian and American investigators, and a meeting was held in Kiev, Ukraine in January to make improvements and revisions to this draft. A second meeting was held in Kiev, Ukraine in February 2000 to finalize the draft proposal. The concept for this proposal is anticipated to be submitted to the NCI DCEG Senior Advisory Group for review and approval at a forthcoming meeting.